

REMARKS

The pending Office Action addresses and rejects claims 1-8, 10-14, 16-21, 23-27, and 32-33. Reconsideration is respectfully requested in view of the above amendments and following remarks.

Rejections Under 35 U.S.C. §112

Claims 1-8, 10-14, 16-18, and 32 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner asserts that the term “greater than about” is “unclear and indefinite because the metes and bounds of the phrase are unclear as to lower limits.” Applicants respectfully disagree with the Examiner’s assertion.

Claim 1 recites, inter alia, an initial modulus of elasticity greater than about 1.5 MPa and an initial suture pull-out strength greater than about 6N. The Examiner cites *Ex Parte Miyazaki*, 89 USPQ2d 1207 (BPAI 2008) for the principle that “if the claim is amenable to two or more plausible claim constructions, the USPTO is justified in requiring applicant to more precisely define the metes and bounds of the claim invention by holding the claim unpatentable under 35 U.S.C. 112, second paragraph, as indefinite.”

However, the pending claims are not amenable to two or more plausible claim constructions according to the reasoning of the Board in *Ex Parte Miyazaki*. To the contrary, the lower limit of the phrase “an initial modulus of elasticity greater than about 1.5 MPa” is clear and amenable to only one plausible claim construction, i.e., that the lower limit for the initial modulus of elasticity is about 1.5 MPa. The lower limit of the phrase “an initial suture pull-out strength greater than about 6N” is likewise clear and amenable to only one plausible claim construction, i.e., that the lower limit for initial suture pull-out strength is about 6N. The Examiner suggests amending the claim to recite “greater than” or alternatively “about,” but not both. Although the claim language is broader than the phrases suggested by the Examiner, the claim language, nonetheless, meets the requirements of 35 U.S.C. §112, second paragraph. It seems the Examiner may be confusing claim breadth for indefiniteness, which the MPEP makes clear is improper. See MPEP 2173.04 (“breadth of a claim is not to be equated with indefiniteness”).

Moreover, the Examiner has conceded that the term "about" does not suffer from indefiniteness. As such, the addition of the term "greater than" cannot render the concept of "about 6N" indefinite. Likewise, the Examiner has conceded that the term "greater than" does not suffer from indefiniteness. As such the addition of the term "about" cannot render the concept of "greater than 6N" indefinite. Nevertheless, Applicants add six new claims to recite the language suggested by the Examiner.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112.

Rejections Under 35 U.S.C. §103

Claims 1-8, 10-14, 16-21, 23-27, and 32-33 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,165,217 to Hayes ("Hayes") in view of International Patent Publication No. WO 01/85226 of Huckle et al. ("Huckle"), U.S. Patent Publication No. 2002/0127265 of Bowman et al. ("Bowman"), and U.S. 6,005,161 to Brekke ("Brekke"). Applicants respectfully disagree with the Examiner's rejection.

Independent claim 1 recites a biocompatible meniscal repair device. The device includes a scaffold that has an initial modulus of elasticity greater than about 1.5 MPa and an initial suture pullout strength greater than about 6 N. Independent claim 19 recites a biocompatible meniscal repair device including a scaffold wherein the scaffold provides increased suture pull-out strength and has an initial modulus of elasticity in the range of about 1.5 MPa to 40 MPa.

Hayes fails to teach or suggest the claimed invention.

Hayes fails provide any teaching or suggestion regarding a scaffold that has an initial modulus of elasticity greater than about 1.5 MPa. The Examiner argues that "Hayes also teach the nonwoven scaffolds have a shear strength in excess of 1.4 MPa." However, shear strength is not a modulus of elasticity. Modulus of elasticity is the ratio of stress to strain. Indeed, the Examiner notes that "Young's Modulus (MPa) is defined as the linear proportional constant between stress and strain." Office Action at page 5. Shear strength and modulus of elasticity both have the same units because modulus of elasticity is the ratio of stress to strain and strain is dimensionless. However, shear strength and modulus of elasticity are not equivalent. Hayes only discloses the shear strength of various materials, not the modulus of elasticity of those materials. Hayes defines shear strength in terms of a shear stress (MPa) and max load (N). There is no teaching or suggestion in

Hayes regarding the modulus of elasticity. Hayes also fails to disclose any strain values or any data from which a strain could be calculated. Moreover, the lap shear tests performed by Hayes have no relation to the stress and strain values necessary to calculate modulus of elasticity. Hayes therefore fails to provide any teaching or suggestion of materials having the claimed modulus of elasticity.

Hayes also fails to provide any teaching or suggestion regarding a scaffold that has an initial suture pullout strength greater than about 6 N. The Examiner argues that "[t]he requisite suture strength above 6N is also taught in the tables [of Hayes]." The Examiner is incorrect. The table at column 50 of Hayes does not provide any teaching or suggestion of the suture pull-out strength of the disclosed materials. Instead, the table refers to "Max Load (N)." The "Max Load (N)" is apparently the maximum shear force a sample of the disclosed materials was able to withstand before failure in the lap shear tests conducted by Hayes. *See, e.g.*, Hayes at col. 49-50. The lap shear tests performed by Hayes are entirely unrelated to suture pull-out strength. Suture pull-out strength is tested using a very different test methodology from the lap shear tests disclosed by Hayes. *See, e.g.*, published application at paragraphs 0087-0093. The "Max Load (N)" purportedly disclosed by Hayes thus provides no teaching or suggestion regarding the suture pull-out strength of the materials, much less the suture pull-out strength of such materials in a scaffold suitable for use in a method of surgically repairing meniscal defects. Hayes therefore fails to teach or suggest a scaffold that has the claimed initial suture pull-out strength.

Bowman fails to remedy the deficiencies of Hayes.

Bowman fails to remedy the deficiencies of Hayes at least because Bowman fails to teach or suggest a scaffold that has the claimed modulus of elasticity. Bowman also fails to remedy the deficiencies of Hayes because Bowman fails to teach or suggest a scaffold including a dry laid nonwoven polymeric material that has the claimed initial suture pull-out strength.

Bowman, like Hayes, fails to teach or suggest a scaffold that has the claimed modulus of elasticity. The only teaching in Bowman that relates to the modulus of elasticity of the scaffold pertains to the properties of the elastomeric copolymers that are "particularly useful in the present invention." Bowman at par. 0031. Bowman discloses that the elastomeric copolymers "exhibit a percent elongation (e.g., greater than about 200 percent and preferably greater than about 500 percent)." *Id.* Bowman further discloses that "suitable elastomers should also have a tensile strength greater than about 500 psi, preferably greater than about 1,000 psi." *Id.* Such high values for percent elongation at the disclosed values for tensile strength suggest, absent teaching to the contrary in the

reference, that the implant taught by Bowman would be stretchy, i.e., would have a low modulus. Indeed, Bowman teaches that "suitable elastomers exhibit a high percent elongation and a low modulus, while possessing good tensile strength and good recovery characteristics." *Id.* In contrast, Applicants teach that "compared to conventional meniscal implant devices," a scaffold having the claimed modulus of elasticity range "render[s] the scaffold of the present invention better suited to the demanding conditions within the knee joint and can be fixed in place with less risk of the implant migrating or unraveling." Published application at par. 0064. Thus, Bowman fails to disclose the claimed modulus of elasticity and instead suggests a modulus of elasticity that would be lower than the claimed range.

Bowman, like Hayes, also fails to teach or suggest a scaffold having the claimed initial suture pull-out strength that includes a dry laid nonwoven polymeric material. The Examiner alleges that, according to Bowman, "[t]he suture pull-out strength on day zero of a foamed mesh scaffold is taught as being in the range of 5.7 +/- 0.3 (which is read as being in the range of greater than about 6N)." However, the suture pull-out strength disclosed by Bowman is for a "foam reinforced with an embedded VICRYL knitted mesh," not a scaffold including a dry laid nonwoven polymeric material, e.g., as required by claim 1. Nonwoven materials are entirely different from the mesh disclosed by Bowman. Indeed, Applicants disclose that "[t]he term 'nonwoven' as used in the present invention, and as understood by one skilled in the art, *does not include woven, knit, or mesh fabrics.*" See Published Application at Paragraph [0050] (emphasis added). Thus, a non-woven material is not a mesh material or even equivalent to a mesh material. In fact, the mesh material disclosed by Bowman represents an entirely different composition from the non-woven material of the present invention. The suture pull-out strength data disclosed by Bowman is relevant only for a foam reinforced with a mesh. Bowman therefore provides no teaching or suggestion regarding the claimed initial suture pull-out strength for a scaffold including a nonwoven material.

Huckle and Brekke also fail to remedy the deficiencies of Hayes.

Huckle and Brekke also fail to remedy the deficiencies of Hayes at least because these references also fail to teach or suggest a scaffold that has the claimed modulus of elasticity or a scaffold having the claimed initial suture pull-out strength. Indeed, there is no teaching or suggestion in either reference regarding any modulus of elasticity or suture pull-out strength for scaffold materials. The Examiner does not allege otherwise, instead relying on Huckle and Brekke to remedy other deficiencies of Hayes.

The cited references, alone or in combination, fail to teach or suggest the claimed invention.

As discussed above, Hayes, Bowman, Huckle, and Brekke each fail to teach or suggest a scaffold including a dry laid nonwoven polymeric material that has an initial modulus of elasticity greater than about 1.5 MPa or an initial suture pull-out strength greater than about 6N. Thus, even if the references were combined, the combination would also fail to teach or suggest Applicants' claimed invention.

Accordingly, claims 1 and 19 distinguish over the combination of Hayes, Bowman, Huckle, and Brekke and represent allowable subject matter. Claims 2-8, 10-14, 16-18, 20, 21, 23-27, and 32-33, which depend from either claim 1 or 19, distinguish over the cited art at least because they depend from an allowable base claim.

Obviousness-Type Double Patenting Rejections

The Examiner rejects claims 1-8, 10-14, 16-21, 23-27, 32, and 33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over:

- i. claims 1-6, 8, and 10 of U.S. Patent No. 6,884,428 in view of Hayes, Huckle, Bowman and Brekke;
- ii. claims 1-6 and 8 of U.S. Patent No. 6,852,330 in view of Hayes, Huckle, Bowman and Brekke;
- iii. claims 1, 2, 7-9, and 13-16 of U.S. Patent No. 6,599,323 in view of Hayes, Huckle, Bowman and Brekke;
- iv. claims 1 and 8-11 of co-pending Application No. 11/856,743 in view of Hayes, Huckle, Bowman and Brekke;
- v. claims 1, 5, 7-9, 12, and 13 of co-pending Application No. 11/856,741 in view of Hayes, Huckle, Bowman and Brekke;
- vi. claims 1, 3-6, 13-18, 20-21, 42-47 of co-pending Application No. 10/775,034 in view of Hayes, Huckle, Bowman and Brekke;
- vii. claims 1, 2, 4, 6-15, 30-37 of co-pending Application No. 10/828,841 in view of Hayes, Huckle, Bowman and Brekke;

- viii. claims 1-5, 7, 9, 10, 12, 14-19, and 28 of co-pending Application No. 11/729,046 in view of Hayes, Huckle, Bowman and Brekke;
- ix. claims 98-119 of co-pending Application No. 10/374,772 in view of Hayes, Huckle, Bowman and Brekke, as well as Vyakarnam et al., (U.S. Patent No. 6,534,084), Albrecht et al. (Arch. Orthop. Trauma Surg. 1983:213-217), Naughton et al., (U.S. Patent No. 5,842,477), and Chvapil (U.S. Patent No. 5,078,744).

Applicants will file appropriate terminal disclaimers if so warranted. However, each of the Examiner's double patenting rejections relies on the combination of Hayes, Huckle, Bowman and Brekke. As claims 1-8, 10-14, 16-21, 23-27, 32, and 33 of the present application distinguish over Hayes, Huckle, Bowman and Brekke for at least the reasons discussed above, Applicants submit that the Examiner's double patenting rejections lack basis for those same reasons.

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

By _____/Christopher J. Stow/_____
Christopher J. Stow
Registration No.: 67,003
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617)439-2541
(617) 310-9541 (FAX)
Attorney for Applicants